Value of a supervised exercise program for the therapy of arterial claudication

Robert B. Patterson, MD, Bernadine Pinto, PhD, Bess Marcus, PhD, Andrea Colucci, RN, Tina Braun, RN, and Mary Roberts, MS, *Providence, R.I.*

Purpose: This study was performed to test the effectiveness of a formal supervised exercise program against a home-based exercise program for both walking ability and quality of life endpoints.

Methods: Patients with arterial claudication were randomized to either a 12-week supervised exercise program (SUPEX) with weekly lectures relating to peripheral vascular disease or to a home exercise group (HOMEX) who attended an identical lecture program and received weekly exercise instruction. The study population included 29 men and 26 women, with a mean age of 69.1 ± 8.1 years. Forty-seven patients completed the 12-week program, 46 were available for testing at completion, and 38 for 6-month testing. Claudication pain time (CPT) and maximum walking time (MWT) on a progressive treadmill exercise test were assessed at baseline, program completion, and 6 months. The Medical Outcomes Study Short Form-36 (SF-36) was administered at these intervals to assess effects on quality of life.

Results: Each group improved ($p < 0.001$) in both CPT and MWT at the completion of the 12-week program, which was sustained at the 6-month follow-up. Increase in HOMEX CPT from baseline (3.6 ± 2.73 minutes) to 6-month follow-up (6.6 ± 3.17 minutes) was less than for the SUPEX group (3.8 ± 2.74 to 11.2 ± 4.02 minutes, respectively); similar results were obtained for MWT. At both completion and 6 months, there was a significant intergroup difference for CPT and MWT ($p < 0.004$) favoring SUPEX. For both groups, measures of health perception based on the SF-36 demonstrated improvement ($p < 0.002$) in Physical Function Subscale, Bodily Pain Subscale, and Physical Composite Score. There were no between-group diffences on the subsets of the SF-36 at the three assessment intervals.

Conclusions: Supervised exercise programs provide superior increased walking ability in the noninterventional therapy of arterial claudication, and both supervised and home based exercise therapy result in improved SF-36 functional measures. The lack of intergroup differences in these measures may be a result of the high degree of interaction with healthcare providers in the HOMEX group. Although a supervised program results in optimal walking benefits, a highly structured home-based program provides similar functional improvement and may be a satisfactory alternative for patients with lesser walking requirements. (J Vasc Surg 1997;25:312-9.)

From the Department of Surgery, Division of Vascular Surgery (Dr. Patterson, Ms. Colucci, and Ms. Braun), and the Department of Psychiatry and Behavioral Medicine (Drs. Pinto and Marcus, and Ms. Roberts), Brown University School of Medicine.

Supported by grant #9307853S from the American Heart Association, Rhode Island Affiliate.

Presented at the Forty-fourth Scientific Meeting of the International Society for Cardiovascular Surgery North American Chapter, Chicago, Ill., June 9-10, 1996.

Reprint requests: Robert B. Patterson MD, Division of Vascular Surgery, The Miriam Hospital, 164 Summit Ave., Providence, RI 02906.

0741-5214/97/$5.00 + 0 **24/6/78286**

Arterial claudication represents a major cause of morbidity in the elderly, with an annual incidence of approximately 20 per 1000 in men and women over age 65.[1] This represents an estimated increase in disabling claudication of more than 1 million symptomatic elderly patients every 2 years during the next 50 years.[2] Although invasive interventions have recently been endorsed by an interdisciplinary committee[3] for the therapy of incapacitating claudication, exercise training has also proven to be effective in improving objective treadmill performance[2] and community-based walking ability.[4]

Randomized trials that have reported improvement in exercise performance after training have used nonexercising control groups (i.e., patients in-

Table I. Patient attrition during course of study and reason for loss from study

	Time of dropout			
Reason	*Program onset*	*During program*	*At posttest*	*At 6-month follow-up*
Medical	HOMEX - 0 SUPEX - 1	HOMEX - 4 SUPEX - 0		HOMEX - 2 SUPEX - 3
Refusal	HOMEX - 0 SUPEX - 1	HOMEX - 1 SUPEX - 1	HOMEX - 0 SUPEX - 1	HOMEX - 2 SUPEX - 1
Move/job	HOMEX - 2 SUPEX - 1			
Died				HOMEX - 0 SUPEX - 2

structed not to vary their usual activity) for comparison.[4-7] Although this method has confirmed the positive effects of exercise training, the role of direct supervision by trained personnel versus exercise instruction to be performed in a home environment has not been well studied.

Patients with intermittent claudication have a reduced quality of life when measured by a variety of instruments.[8-12] Improvement after intervention (surgery or percutaneous angioplasty) has been suggested in nonrandomized studies,[8,10,13] and exercise therapy has been demonstrated to improve measures of self-perceived health and function compared with nonexercising controls.[12] No study to date has isolated the effect of supervised exercise.

We designed a carefully controlled study to evaluate the benefits of a formal supervised exercise program compared with a home-based exercise program with weekly interventions in the form of lectures and exercise counseling. Our primary endpoints were exercise performance, based on measured treadmill walking time, with secondary endpoints of measures of health perception.

METHODS

Patient population

Patients between the ages of 50 and 75 with arterial claudication symptoms of greater than 3-months' duration were recruited to the study. On recruitment, the patients underwent hemodynamic eligibility screening. Intermittent claudication from arterial insufficiency was established by resting ankle-brachial index (ABI) of less than 0.9 and a decrease in ankle pressure by 15 mm Hg or more after a standard exercise protocol (10 degree incline, 1.5 mph, 10 minutes of exercise). Patients who did not meet these hemodynamic criteria or had ischemic rest pain or tissue loss were excluded. Those patients who were unable to participate in an exercise program because of limitations of comorbid illness (arthritis, chronic obstructive pulmonary disease, etc.) were also excluded.

Because a significant number of patients with arterial claudication have associated coronary artery disease that may be silent within their limited daily activity, all patients who met the screening criteria outlined above underwent a graded exercise cardiac stress test (EST) by bicycle ergometry.[14] Patients who exhibited no evidence of myocardial ischemia at exercise capacity on a submaximal (80% target heart rate) EST were admitted to the study. Patients with equivocal results were referred to their primary physician for further evaluation. If dipyridamole myocardial perfusion imaging or an alternative cardiac screening method was performed and the level of exercise required by the exercise program was deemed safe, the patient was enrolled. Patients were excluded if exercise-related ischemia was discovered and thought to make exercise therapy unsafe. The study was approved by the Miriam Hospital/Brown University Affiliated Hospitals Institutional Review Board, and informed consent was obtained from all eligible participants.

Eighty-three patients were screened for participation in the study. Twenty-three were deemed ineligible: eight failed cardiac screening, six had nonarterial claudication, four had comorbidities that precluded exercise, and five withdrew for scheduling and transportation problems. To ensure hemodynamic comparability of groups, maximum walking time to limiting claudication (MWT) on the progressive treadmill exercise test at baseline was used to develop three strata, with randomization performed within each strata by computer matrix. Sixty patients were randomized with five more excluded at onset (Table I), equally divided between groups. The study population at entry included 29 men and 26 women with a mean age of 69.1 ± 8.1 years. There was no difference in the demographics of the two groups at entry (Table II).

Study design

Patients with arterial claudication were randomized to either a 12-week supervised exercise program

Table II. Demographic composition of study population

	Whole study (n = 55)	*SUPEX (n = 27)*	*HOMEX (n = 28)*
Average Age	69.3 ± 8.1	67.9 ± 7.5	70.3 ± 8.6
Resting ABI	0.58 ± 0.13	0.57 ± 0.15	0.59 ± 0.12
% Male	52.7	59.3	46.4
% Previous MI	30.9	33.3	28.6
% History CHF	9.1	7.4	10.7
% Hypertension	61.8	70.4	53.6
% Diabetes	34.5	29.6	39.3
% Current smoker	23.6	25.9	21.4
% History of smoking	82.6	90.9	75.0
Average BMI	28.2 ± 4.5	28.8 ± 3.9	27.7 ± 4.9

MI, Myocardial infarction; *CHF,* congestive heart failure; *BMI,* body mass index.

(SUPEX) consisting of three 1-hour sessions per week of treadmill and aerobic exercise with weekly lectures relating to peripheral vascular disease or to a home exercise group (HOMEX) who attended an identical lecture program and received weekly exercise instruction. Walking performance including claudication pain time (CPT) and MWT was assessed at baseline, program completion, and 6 months. The Medical Outcomes Study 36-Item Short Form Health Survey (SF-36) was administered to assess effects on quality of life, social support, and self-reported activity levels.

Supervised exercise (plus lecture) group. After baseline data collection, those patients assigned to the supervised exercise group had an individual exercise prescription established using the guidelines of the American College of Sports Medicine for cardiac and elderly patients.[15] Data from the bicycle stress test was used to determine resting heart rate, peak heart rate, peak blood pressure response to exercise, and metabolic equivalent of oxygen consumption (MET). Estimated energy expenditure in METs was calculated based on achieved workload.* Initial treadmill speed and grade was determined from entry treadmill testing data. The subjects then participated in a standardized 12-week supervised exercise program consisting of three exercise sessions per week of 1 hour duration. The exercise prescription includes an aerobic component consisting of arm and leg ergometry and Air-Dyne cycling (Schwinn Bicycle Company, Chicago, Ill.) designed for cardiovascular training. Claudication-specific exercise periods were performed on the treadmills after the method of Feinberg et al.[16] In addition to recording resting heart rate and blood pressure at the initiation of each session, improvement in CPT was monitored to allow for adjustment of the specific treadmill portion of the exercise program; the exercise prescription was recalculated at 2-week intervals for cardiovascular training. Adherence was assessed by attendance at exercise sessions, and subjects who missed a session were telephoned by the nurse specialist and encouraged to attend make-up sessions.

The exercise program also included weekly health education lectures addressing risk factors for atherosclerosis and their modification as well as overviews of nutrition, exercise, and potential complications of atherosclerotic cardiovascular disease, specifically covering warning signs and symptoms.

Home exercise (plus lecture) group. Subjects in the HOMEX group attended a 12-week program of educational lectures identical to those attended by the SUPEX group. These were scheduled at a different time to avoid intergroup influence. HOMEX subjects were instructed to walk a minimum of three times a week at home to tolerance, for a period of 20 to 40 minutes, in keeping with standard medical practice. Weekly exercise logs were maintained by the subjects and reviewed with the study nurses at the lecture sessions. Individual exercise counseling and review of home protocol was provided by the study nurse at each lecture session. This translated to approximately 1½ hours of direct contact weekly per patient in the HOMEX cohort.

Measures

Exercise and hemodynamic measures. Before randomization, all subjects underwent a graded progressive maximal treadmill exercise test initiated at 1 mph with a grade of 5%, increasing in speed and grade at 5-minute intervals through four stages to 2.5 mph at 10% grade (equivalent of 6.4 METS).

*MET = (VO_2 ml/min ÷ body weight kg) ÷ 3.5.

VO_2 (ml/min) = (3.5 ml/kg/min × body weight kg) + (kg/min × 2).

kgm/min = kilogram meters/minute (power output) calculated from resistance and distance achieved with leg ergometer.

VO_2 = Oxygen consumption.

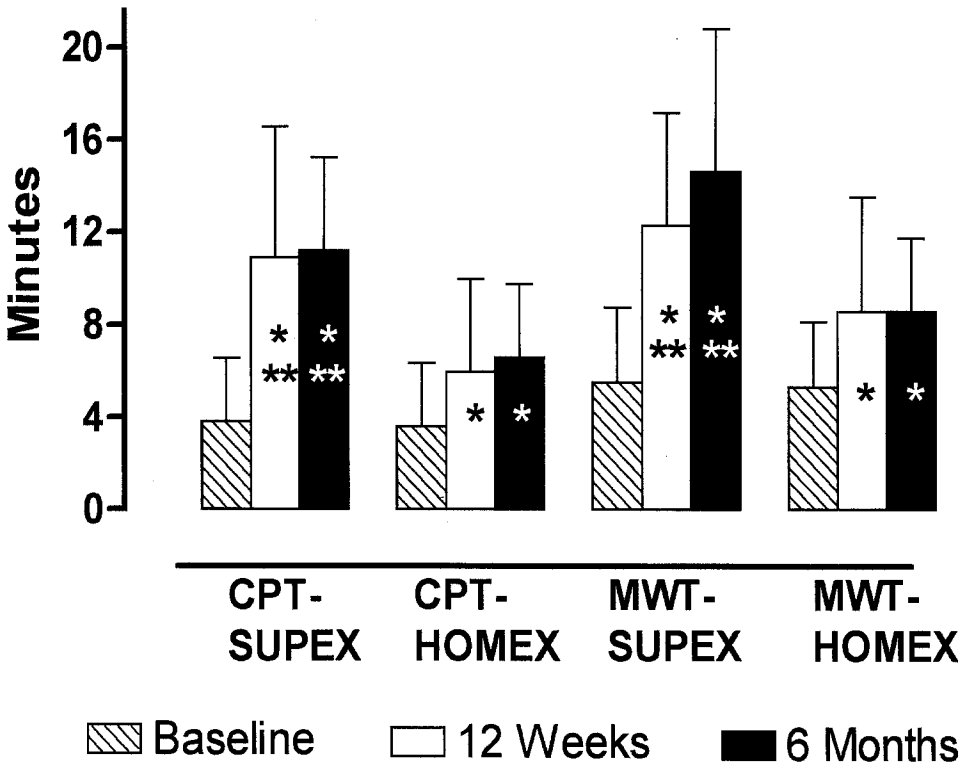

Fig. 1. Values for CPT and MWT in HOMEX and SUPEX groups over course of study. *Difference from baseline, $p < 0.001$; **intergroup difference, $p < 0.004$.

CPT and MWT were measured as specific endpoints. A "familiarization" test was administered at least 3 days before the baseline test to minimize training effect and learning curve. The progressive treadmill test was repeated at 12 weeks (program completion) and 6 months. Resting ankle-brachial indexes and recovery times to self-reported pain relief and to return to baseline ABI were recorded at each interval as well.

Quality of life questionnaire. At pretreatment (baseline), posttreatment (12 weeks) and 6-month follow-up, all subjects were required to complete the SF-36, which was constructed for use in the Medical Outcomes Study and was designed for use in clinical practice and research.[17] The SF-36 assesses eight health concepts focusing on limitations in physical, social, and role activities, bodily pain, mental health, energy/fatigue, and general health perception.

Statistical methods

Data points at baseline, program completion (12 weeks), and follow-up for the CPT and MWT as well as SF-36 were analyzed using repeated measures analysis of variance (ANOVA). Secondary analyses were conducted using paired *t* tests and one-way ANOVAs to determine the direction of significant results obtained from the repeat measures ANOVA. One-way ANOVAs with a Bonferroni correction were run to determine the baseline equivalence of the two groups, which had been stratified for the baseline walking time at randomization. All statistical analyses were conducted with the aid of SPSS for Windows, version 6.0.

RESULTS

Forty-seven of the initial 55 patients completed the 12-week program, 46 were available for testing at completion, and 38 for 6-month testing (three provided questionnaire data only). Patients were lost to the study for medical reasons (10), refusal (7), death (2), and transportation and job factors (3), evenly divided between HOMEX and SUPEX (Table I). No patients required intervention for lower extremity ischemia during the study or in the follow-up period.

At baseline, both groups were matched by performance on the progressive treadmill test. The average CPT was 3.7 ± 2.71 minutes, corresponding to 88 m, with no patient able to walk more than 10.8 minutes (350 m). The average MWT was 5.4 ± 3.00 minutes, corresponding to 145 m of ambulation, with no patient able to walk beyond 14.8 minutes (585 m).

Table III. Scores for SF-36 of SUPEX and HOMEX groups at baseline, program completion, and 6-month follow-up

	Baseline		*Program completion*		*6-month follow-up*	
	SUPEX	*HOMEX*	*SUPEX*	*HOMEX*	*SUPEX*	*HOMEX*
Physical function	43 ± 17.7	41 ± 20.8	52 ± 22.2*	53 ± 24.4*	56 ± 14.4*	54 ± 23.5*
Role-physical function	45 ± 42.2	30 ± 34.7	44 ± 42.2	49 ± 41.6	49 ± 39.7	45 ± 41.0
Pain index	53 ± 20.8	51 ± 20.6	64 ± 23.6*	61 ± 21.6*	62 ± 20.6*	64 ± 19.3*
General health	64 ± 18.9	60 ± 23.0	65 ± 16.8	62 ± 22.8	64 ± 13.8	64 ± 22.5
Vitality score	52 ± 19.9	46 ± 18.9	53 ± 16.9	57 ± 15.9	54 ± 17.9	55 ± 19.5
Social function	81 ± 22.8	80 ± 21.1	87 ± 15.2	82 ± 17.6	81 ± 18.3	88 ± 14.6
Role-emotional health	71 ± 36.6	76 ± 33.8	72 ± 36.3	74 ± 33.3	70 ± 36.0	77 ± 32.6
Mental health	72 ± 18.8	70 ± 18.3	74 ± 14.8	77 ± 13.6	72 ± 16.1	78 ± 13.8
Standard physical component	35 ± 7.1	33 ± 9.4	38 ± 8.3*	38 ± 12.0*	39 ± 8.6*	38 ± 11.1*
Standard mental component	53 ± 9.6	53 ± 9.0	53 ± 8.3	54 ± 8.2	51 ± 10.2	55 ± 7.3
Walk 1+ miles	1.2 ± 0.5	1.2 ± 0.5	1.3 ± 0.5*	1.5 ± 0.7*	1.3 ± 0.5*	1.5 ± 0.6*
Walk many blocks	1.26 ± 0.5	1.39 ± 0.6	1.75 ± 0.7*	1.96 ± 0.8*	1.72 ± 0.7*	1.75 ± 0.8*
Walk 1 block	1.70 ± 0.7	1.86 ± 0.7	2.04 ± 0.9*	2.52 ± 0.7*	2.44 ± 0.5*	2.45 ± 0.8*

There was no statistically significant intergroup difference at any interval.
*Difference from baseline, $p < 0.01$.

Improvement in CPT and MWT was seen in both groups (Fig. 1) at completion of the 12-week study, which was sustained at 6-month follow-up ($p < 0.001$). The HOMEX group had improvement in both CPT and MWT of 131% and 70% respectively versus 337% and 207% for the SUPEX group ($p < 0.004$). The actual improvement in the SUPEX group is underestimated as a result of three patients walking beyond the fourth stage (20 minutes) of the graded exercise test for both CPT and MWT. In the HOMEX group one patient walked beyond 20 minutes for MWT only. Time to return to baseline ABI and time to self-reported pain relief was no different at baseline between groups and demonstrated no significant change at either posttesting or 6-month follow-up.

There were no differences at baseline between treatment groups on the eight standard subscales of Physical Function, Role-Physical Function, Pain Index, General Health, Vitality Score, Social Function, Role-Emotional, or Mental Health (Table III). Similarly, composite scores of Physical and Mental Components and the three individual walking items were no different at baseline.

At posttesting, scores on Physical Function, Bodily Pain, and Physical Composite, as well as walking 1+ miles, many blocks, and 1 block improved for both SUPEX and HOMEX ($p < 0.01$), with no intergroup differences. This improvement was unchanged at follow up for both groups (Table III).

DISCUSSION

Exercise therapy for intermittent claudication is effective in the relief of debilitating symptoms, with improvements in claudication pain distance of 179% and in distance to maximum claudication pain of 122% found in a recent meta-analysis of 21 studies.[2] Of these studies, 11 were performed at an on-site facility supervised by trained personnel, two were solely home-based, and eight combined on-site and home-based programs. Although the authors identified several components of exercise programs that correlated with increasing improvement in walking ability, they noted no difference in outcome between on-site and combined programs. The majority of these studies, however, were nonrandomized or uncontrolled, and the three randomized controlled studies included in the analysis used nonexercising controls.

Our results support the superiority of walking distance improvement in patients who participate in a supervised exercise program. The group improvement for SUPEX is underestimated because of limitations at the upper end of the graded treadmill exercise test, but conservatively translates into an improvement of 190 additional meters of pain-free treadmill walking and 290 meters of maximal treadmill walking over the HOMEX group at 6-month follow-up. Although the possibility of some treadmill training effect exists in the SUPEX group, the HOMEX group walked well into the third stage of the progressive test at completion and follow-up. A previous study[18] found improvement in walking on a less-rigorous static treadmill test (between 3.2 and 5.4 km/h at no grade) underestimated free walking distance improvement by 50%, suggesting an improvement in clinical walking ability for the SUPEX group in excess of four blocks over baseline. We have

added an additional stage to our graded progressive treadmill test to avoid the truncation of walking improvement in future studies.

The baseline scores on the SF-36 are significantly depressed in Physical Function and General Health compared with patients without chronic conditions in the Medical Outcomes Study,[15] and are comparable with patients with congestive heart failure, myocardial infarction, and chronic lung problems. Responses to Mental Health and Social Function questions were less affected, in keeping with the findings in other populations with chronic medical conditions. Our patients' scores were comparable with other patients with peripheral arterial disease who undergo elective surgery.[11] The improvement with time in the scores of both the HOMEX and SUPEX groups are consistent with the findings of Regensteiner et al.,[12] who found improvement in physical functioning score in patients who underwent 24 weeks of supervised treadmill exercise but no significant change in their control (initially nonexercising) or strength training group. A retrospective, cross-sectional study of patents having undergone invasive (i.e., bypass or endoluminal revascularization) or noninvasive therapy suggested improvement in patients' perception of their health and well-being as measured with the SF-36 when treated invasively, but not when managed noninvasively.[13] There was no exercise therapy arm in this retrospective study, with their noninvasively managed patients representing more traditional approaches to nonoperative management.

The lack of differences between the HOMEX and SUPEX groups in improvement in quality of life measures are not surprising given the rigorous nature of our control group. To replicate a clinical program of exercise therapy for claudication and to control solely for the effects of exercise supervision, we exposed the HOMEX group to the same series of weekly lectures as our SUPEX group. To monitor their degree of home exercise, they maintained weekly activity logs that were reviewed at each lecture session with the program nurse. They also were afforded the opportunity to have individual exercise counseling with the nurse at these sessions to answer questions regarding their activity and progress. Other than the absence of direct, monitored exercise supervision, the groups received far more intervention than is customarily available to the patient who goes to his primary physician or surgeon with complaints of intermittent claudication.

Optimal methods for assessing quality of life in patients with peripheral arterial disease have not been established. The SF-36 has generally been administered to large patient samples (more than 200); even in such samples the standard deviations for the scores are high.[19,20] In addition to the SF-36, the Nottingham Health Profile,[9] the EuroQuol,[10] and the McMaster Health Index Questionnaire[21] have been used to assess quality of life and consistently demonstrate impairment in quality of life measures in patients with intermittent claudication when compared with healthy, age-matched controls. The confounding effects of the many comorbidities that affect patients with intermittent claudication are difficult to control for and may account for the lack of change after an exercise program in parameters not directly related to pain and physical function.

As optimal means for treatment of arterial claudication are sought and with an increasing population of patients at risk, specifics of design of programs for the noninterventional therapy of this disease become increasingly important. Third-party carriers and managed care providers do not uniformly provide reimbursement for exercise therapy of claudication, despite a growing body of evidence documenting the efficacy of these programs. Our study confirms superior improvement in walking ability as measured with objective treadmill testing with a formal, supervised exercise program over an intensive home-based program. The objective improvement in quality of life with both exercise protocols may be a result of the intensive support from the nurses and therapists supervising the program. For those patients who do not require maximum freedom from claudication to perform their daily activities, a highly structured, intensive home-based program may be a satisfactory alternative. A supervised program results in optimal walking improvement and should be compared with other interventions (angioplasty, surgery) for both walking and quality of life improvement.

REFERENCES

1. Kannel WB, McGee DL. Update on some epidemiologic features on intermittent cladication: the Framingham Study. J Am Geriatr Soc 1985;33:13-8.
2. Gardner AW, Poehlman ET. Exercise rehabilitation programs for the treatment of claudication pain: a meta-analysis. JAMA 1995;274:975-80.
3. Pentecost MJ, Criqui MH, Dorros G, Goldstone J, Johnston KW, Martin EC, et al. Guidelines for peripheral percutaneous transluminal angioplasty of the abdominal aorta and lower extremity vessels. Circulation 1994;89:511-31.
4. Hiatt WR, Regensteiner JG, Hargarten ME, Wolfel EE, Brass EP. Benefit of exercise conditioning for patients with peripheral arterial disease. Circulation 1990;81:602-9.
5. Dahloff AG, Bjorntorp P, Holm J, Schersten T. Metabolic activity of skeletal muscle in patients with peripheral arterial

insufficiency: effect of physical training. Eur J Clin Invest. 1974;4:9-15.
6. Holm J, Dahllof AG, Bjorntorp P, Schersten T. Enzyme studies in muscles of patients with intermittent claudication: effect of training. Scand J Clin Lab Invest. 1973;31(suppl 128);201-5.
7. Larsen OA, Lassen NA. Effect of daily muscular exercise in patients with intermittent claudication. Lancet 1966;2: 1093-6.
8. Bosch JL, Hunink MGM, Tetteroo E. Improvement in quality of life after revascularization for aortoiliac arterial disease. Presented at Society for Medical Decision Making, Tempe, Ariz., Oct. 1995.
9. Khaira HS, Hanger R, Shearman CP. Quality of life in patients with intermittent claudication. Eur J Vasc Endovasc Surg 1996;11:65-9.
10. Cook TA, O'Regan M, Galland RB. Quality of life following percutaneous transluminal angioplasty for claudication. Eur J Vasc Endovasc Surg 1996;11:191-4.
11. Mangione CM, Donaldson MC, Cook EF, Whittemore AD, Lee TH, Mannick JA. Perception of change in health status among patients undergoing elective vascular surgery. In: Greenhalgh RM, Fowkes FGR, editors. Trials and tribulations of vascular surgery. London: W.B. Saunders, 1996:1-5.
12. Regensteiner JG, Steiner JF, Hiatt WR. Exercise training improves functional status in patients with peripheral arterial disease. J Vasc Surg 1996;23:104-15.
13. Reifler DR, Feinglass J, Slavensky R, Martin GJ, Manheim L, McCarthy WJ. Functional outcomes for patients with intermittent claudication: bypass surgery versus angioplasty versus noninvasive management. J Vasc Med Biol 1994;5:203-11.
14. Ellestad MH, Blomqvist CG, Naughton JP. Standards for adult exercise testing laboratories. American Heart Association Subcommittee on Rehabilitation Target Activity Group. Circulation 1979;59:421A.
15. Exercise testing and prescription for children, the elderly, and pregnancy. In: Kenney WL, Humphrey RH, Bryant CX, et al., editors. American College of Sports Medicine Guidelines for Exercise Testing and Prescription. 5th ed. Philadelphia: Williams & Wilkins, 1995:220-40.
16. Feinberg RL, Gregory RT, Wheeler JR, Snyder SO Jr, Gayle RG, Parent FN III, Patterson RB. The ischemic window: a method for the objective quantitation of the training effect in exercise therapy for intermittent claudication. J Vasc Surg 1992;16:244-50.
17. Stewart AL, Greenfield S, Hays RD, Wells K, Rogers WH, Berry SD, et al. Functional status and well-being of patients with chronic conditions: results from the medical outcomes study. JAMA 1989;262:907-13.
18. Carter SA, Hamel ER, Paterson JM, Snow CJ, Mymin D. Walking ability and ankle systolic pressures: observations in patients with intermittent claudication in a short-term walking exercise program. J Vasc Surg 1989;10:642-9.
19. Stewart AL, Hays RD, Ware JE. The MOS Short-Form General Health Survey: reliability and validity in a patient population. Med Care 1988;27:724-35.
20. McHorney CA, Kosinski M, Ware JE. Comparisons of the costs and quality of norms for the SF-36 health survey collected b mail versus telephone interview: results form a national survey. Med Care 1994;32:551-67.
21. Barletta G, Perna S, Sabba C, Catalano A, O'Boyle C, Brevetti G. Quality of life in patients with intermittent claudication: relationship with laboratory exercise performance. Vascular Medicine 1996;1:3-7.

Submitted June 14, 1996; accepted Sep. 27, 1996.

DISCUSSION

Dr. Walter J. McCarthy III (Chicago, Ill.). The authors are to be congratulated on the design of this carefully randomized prospective trial. They randomized 55 patients who were selected to be the most likely to benefit from an exercise program, that is, patients younger than 75 years of age and without complicating comorbidities that would interfere with an exercise program, such as arthritis, chronic obstructive pulmonary disease, or coronary disease.

They defined patients who had claudication with the most sophisticated evaluation, using an ABI decrease of 0.15 with treadmill exercise testing. Finally, their end points were based on graded, progressive treadmill testing, which is generally thought to be the optimal way to accomplish this testing. The survey instruments included the MOS SF-36, which has very wide recognition and acceptance, and other instruments that are widely accepted. In fact, this paper really is a showcase for the facile use of survey instruments.

The home exercise group exercised at home and the supervised group with exercise equipment, including treadmills. The results were gratifying in both groups, with a roughly 170% increase at home and 280% increase in the supervised group. And these differences were significant between groups.

This brings me to my questions. I think the most serious criticism of this manuscript will stem from the fairly well-established observation that people learn to walk on treadmills by using them. Thus your supervised group, having exercised with treadmills, have a marked advantage that possibly explains their superior performance. Notice that their self-reported physical function was about equal. I wonder whether you could address how significant you think that experience on the treadmill was.

Second, tell us how many patients had iliac disease as compared with superficial femoral-based disease. And did the level of the disease or the initial ABI impact on their improvement potential?

Finally, tell us how this information applies to the more general cohort of patients with claudication that we see, including those who are older, patients that are in their 80s, for example, and those with multiple comorbidities.

Dr. Robert B. Patterson. Thank you, Dr. McCarthy for your comments. With respect to treadmill training, we recognize that people do learn to walk on a treadmill more efficiently. We attempted to control for that by having every patient undergo some treadmill testing and training before the baseline treadmill test.

In terms of the breakdown between iliac and femoropopliteal disease, I am afraid I cannot give those data to you now. We are going to look at disease location as a factor in a larger group to include patients from a clinical program. In this study population there was no difference in response with regard to their resting ABI. In fact, what seems to be the greatest difference in response is something that my behavioral medicine colleagues are investigating now, that people have different approaches to exercise and attitudes toward their health. It may be possible to identify people who would be more likely to benefit from a program such as this.

This brings me to the patient application portion of your question. We have found, particularly in our clinical program, that exercise therapy is applicable to a wide variety of patients. We have successfully treated many octogenarians, as well as patients with renal failure and significant heart disease. The truly problematic patients are those who would not benefit from iliac artery angioplasty or surgery, the patients with debilitating arthritis or chronic obstructive pulmonary disease, who indeed claudicate, but when they are exercised it is frequently their comorbid illness that is limiting in their daily activities.

Dr. Bruce M. Elliott (Charleston, SC). That was simply an elegant study, and I thoroughly enjoyed it. We all have observed that an important component of improvement on claudication is the cessation of smoking. I was wondering whether perhaps you had a large number of patients who were active smokers at entry, what the success rate in quitting was, and was there a difference between those who were closely supervised versus those who were at home?

Dr. Patterson. Some of the original work that is presented on this is Dr. Williams' work, where a large number of patients who entered their program who were smokers who were successful in quitting and had a very durable result. Actually, only 25% of our patients were currently smoking, and we did not address smoking cessation as an issue for them. Most of our patients had a history of smoking, but many had already quit when they came to us.

Dr. Roger Greenhalgh (London, United Kingdom). I liked this study for various reasons. It is of great importance that we determine the optimal exercise program for patients, if for no other reason that we need to combine other treatments with exercise, against exercise alone, to see whether these other treatments have any benefit. And so we must first know what is the optimal exercise program.

There has been difficulty on both sides of the Atlantic in determining an optimal end point, and you have quoted claudication time and walking time. There has to be some caution in regarding these as objective, because, indeed, they are not truly objective. They relate to the moment at which those patients decide they are going to stop walking or when the claudication occurs. So there is a subjective element to it. Indeed, there is poor repeatability for any patient of the claudication and walking time. Our group puts the walking time range at something like 1½ minutes. Therefore, if the variation is 1½ minutes, and the end point is not truly objective, then a little caution is required in determining this best exercise program.

Dr. Patterson. Thank you, Dr. Greenhalgh. The use of a progressive treadmill test seems to help in stratifying these patients more carefully. And I agree with you, it is more that it is an easily measured end point than one that is truly objective. It is based on the subjective response of the patient.

Dr. Stefan A. Carter (Winnipeg, Manitoba, Canada). Similar results were presented at this meeting that also showed, as you did, that a supervised treadmill walking program was superior to a home program. In terms of accessibility and costs, I would like to make a comment that it is possible to train people not on a treadmill and not in the hospital but in a rehabilitation facility or even in shopping malls if they do it consistently. That is what we have done in Winnipeg, where we have trained people in a rehabilitation facility and they achieved walking ability of walking more than a mile, in more than 80% of patients, at a speed of 2 to 3 miles an hour. In terms of need in the community, this is obviously excellent and much as what you have indicated. This may be possible for many people.

Also, we see people in the lab who are referred because somebody cannot feel their pulses, who have grossly abnormal ABIs and who can walk without limitations up to a mile. And there is no reason to doubt it because we have the same kind of patients in our exercise program. I agree that level of disease does not influence it; people with bilateral disease and with ABIs at 0.5 or less can do well.

I have one question. You indicated that at entry you are taking people with duration of symptoms, I believe, of 3 months or more. I believe that there are data that show that patients can improve their claudication distance spontaneously for up to a year or more, and in some of them blood flow after reactive hyperemia or even their ankle-brachial index do improve somewhat. So I wonder whether there is a difference between people with short and longer duration of symptoms at entry.

Dr. Patterson. Thank you, Dr. Carter. I do not have the exact numbers with me, but most of our patients had significantly longer duration of symptoms than 3 months. Most of them had had claudication for several years. We used three months as an arbitrary cutoff to avoid having patients who had the recent onset of symptoms, many of whom get somewhat better very quickly. In addition, frequently patients that were referred to this study were patients who had undergone angioplasty or surgery in the past that had failed. If it was several years ago, we were willing to accept them into the study, but certainly no one was accepted who had undergone any recent interventions.